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| 10/528,191 | 11/08/2005 | Werner Back | 060953-0137 | 6627 |
| 23428 7590 02/17/2010 FOLEY AND LARDNER LLP SUITE 500 3000 K STREET NW WASHINGTON, DC 20007 | | | | |
| EXAMINER | | | | |
| KING, FELICIA C | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/528,191

Applicant(s)

BACK ET AL.

Examiner

FELICIA C. KING

Art Unit

1794

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 October 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 8, 9 and 16-22 is/are pending in the application.
- 4a) Of the above claim(s) 10-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8, 9 and 16-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-06)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This Office Action is written in response to Applicants' Remarks filed 10/19/09.

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 1-6, 8-9 and 16-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marshall et al. (U.S. 4,678,673) and further in view of Jiménez et al. (Proceedings of the 9th International Lupin Conference June 2009 – Applicants' NPL) and Olmos-Dichara et al. (Biotechnology Letters, Vol. 19, No. 8, August 1997 pp 709-714).

Regarding Claims 1-3: Marshall teaches oilseed products that are fermented with microorganisms including *L. casei ssp. rhamnosus*, which produces diacetyl and acetylmethylcarbinol (AMC); the fermented oilseed products have a buttery or dairy-like flavor (i.e. milk-like aroma) and are useful in preparing imitation dairy products such as imitation cream cheese products, i.e., yogurt, cheese, ice cream and other dairy products, derived from oilseed components as milk or caseinate replacers (Abstract; col. 1, lines 5-13). The dairy-like flavors are the result from the bacterial production of two compounds namely diacetyl and AMC, which are produced in soymilk (col. 1, lines 43-50). Marshall also teaches fermentation process for manufacturing dairy-like products from a variety of vegetable oilseeds, such as peanut, cottonseed, rapeseed, sunflower seed and especially soybean, and mixtures thereof (col. 3, lines 52-60). Marshall cites that diacetyl, ACM, including lactic acid, are compounds producing the buttery, milk-like flavors in milk products, which are produced by the fermentation of the oilseeds (col. 7, lines 1-6, 30-38; col. 8, lines 8-49; col. 10, lines 44-59). Marshall also discloses diacetyl produced at 4.3 ug/g, 14.2 ug/g, 21.4 ug/g and 28.7 ug/g [col.7, Table III], which corresponds to 4.3 ppm, 14.2 ppm, 21.4 ppm and 28.7 ppm as is known in

the art. Further, as Marshall discloses, diacetyl inherently produces milk-like aroma and it would have been obvious to add the sufficient amount of diacetyl to produce the desired degree of aroma, i.e. stronger diacetyl content will create more milk-like aroma. Marshall teaches protein preparation produced to a level of 96% total solids made from soybeans (col. 5, lines 39-62; col. 8, lines 1-3; col. 14, lines 5-10 (claim 3)). Marshall teaches oilseed preparations and mentions a variety of other types of oilseeds that are used, but does not specifically mention lupine seeds as a fermented oilseed, although lupine seeds contain oil. However, Jiménez discloses that lupin seeds (alternate spelling for lupine) have high protein contents (35% -48%) and up to 15% lipid (oil/fat) content and compares favorably with soybeans [pg 442, Introduction] and also discloses fermenting the lupin seeds with probiotic microorganisms in order to produce a milk or yogurt like food product [Title pg. 442]. Additionally, Olmos-Dichara discloses that *L. casei ssp. rhamnosus* produces lactic acid and that 95% of the lactic acid produced is in the form of L-lactic acid [Table 1, pg 711].

At the time of the invention it would have been obvious to one of ordinary skill in the art having Marshall, Jiménez, Olmos-Dichara to substitute the soybean in Marshall for the lupine in Jiménez because Jiménez discloses that lupin seeds have a protein and oil contents that compare favorably with soybean and that lupin seeds can be successfully fermented. Further, since lupine seeds can be substituted for soybeans, fermenting lupine seeds with the L-lactic acid producing *L. casei ssp. rhamnosus* as disclosed by Marshall and Olmos-Dichara can be reasonably expected to produce diacetyl and lactic acid thereby creating a milk-like aroma, as taught by Marshall. Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made, to use lupine seeds instead of Marshall's oilseeds and to modify as necessary the reactants (i.e. lupine seeds and *L. casei ssp. rhamnosus* amounts) to produce the desired amounts of diacetyl, lactic acid, which are required to produce the desired milk-like aroma in the protein preparations for

optimal product, i.e., food product, pharmaceutical product, or probiotic nutraceutical, that will have beneficial organoleptic properties for the consumer.

Further, for exemplary purposes, Jiménez discloses where its product contains .8% to 1.0% acidity after 8 hours of fermentation with the probiotic, *L. delbrueckii spp bulgaricus* [pg. 442, Fermentation of Lupin milk] and more explicitly discloses where after 8 hours the final product contained .87% lactic acid [pg. 444, Fermentation of Lupin Milk]. Examiner notes that this is disclosed herein to show that production of lactic acid within the claimed ranges is possible at 8 hours. Therefore, although Marshall does not disclose where the lactic acid content is at least 1%, it does disclose the lactic acid content at between 1.2 mg/g and 2.3 mg/g after 4 hours of fermentation where fermentation time, and amount of initial starter culture are likely factors in the level of lactic acid produced. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to modify the factors that cause the microorganism to produce the amount of lactic acid desired for the intended application, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272.

Regarding Claim 4: Marshall is taken as cited above; L-lactic acid is one of two optical isomers of lactic acid predominantly produced by pyruvate (Wikipedia definition of L-lactic acid), and is an inherent component of lactic acid. Marshall teaches fermentation process to stimulate flavor production with *L. casei* organism in the presence of pyruvate, acetate or citrate (col. 10, lines 17-35). Further as discussed above, Olmos-Dichara discloses where *L. casei ssp. rhamnosus* produces lactic acid and that 95% of the lactic acid produced is in the form of L-lactic acid [Table 1, pg 711].

Regarding Claim 5: Marshall is taken as cited above; protein preparation made from lupine seeds, which is a plant source has inherent properties such as, lactose-free and cholesterol-free.

Regarding Claim 6: Marshall discloses fermentation process which is carried out by a probiotic, particularly *Lactobacillus casei ssp. rhamnosus* as discussed above.

Regarding Claims 8-9, 21 and 22: Marshall teaches imitation dairy products (e.g. protein preparation from oilseed, such as soy beans) which further comprises additional food, flavoring, and functional components such as non-fat dry milk, stabilizers (e.g. carob bean gum), emulsifiers (e.g. mono and diglycerides of edible fatty acids), melting salts (e.g. sodium citrate), flavor agents and food grade acids (e.g. lactic acid) that may be utilized, alone or in combination to provide desirable flavor, texture, other properties, and they may be utilized at weight percent levels based on the total weight of the imitation dairy product (col. 3, lines 7-34). Further, Marshall teaches that the most effective fermentation pH range should be carried out between pH 6.0 and 7.0 [Marshall col. 5, lines 1-8]. Regarding the properties of the protein preparation recited at claims 8-9 and 21 such as the emulsifying activity of the protein preparation at various strengths that applicant has recited, these are properties of the protein preparation and it is being held that the combination of references renders such properties obvious and would have been obvious to the skilled worker who would substitute the soybean of Marshall with the lupin seeds of Jiménez.

For the reasons discussed above, it would have been obvious to a person of ordinary skill in the art at the time of the invention to substitute soybeans with lupine seeds, and in doing so, the properties of emulsifying and foaming activity would have been rendered obvious.

Regarding Claim 16: Marshall discloses that diacetyl, ACM, including lactic acid, are compounds producing buttery, milk-like flavors in milk products, which are produced by the fermentation of oilseeds (col. 7, lines 1-6, 30-38; col. 8, lines 8-49; col. 10, lines 44-59) by microorganisms but does not disclose lupine seeds as discussed above. Jiménez discloses fermenting lupine seeds as discussed above.

Regarding Claim 17: Marshall discloses the fermentation process starting from dry, clean, whole soybeans, grinding, pre-treating, pasteurizing, adding sodium acetate, fermenting with *L. casei* culture, drying, producing to a level of 96% total solids (col. 3, line 60 through col. 4, line 50; col. 5, lines 39-62). Marshall further teaches that the fermentation process may be enhanced by selecting fermentation enhancing agents or as a concentrated paste harvested from milk medium and stored in liquid nitrogen (col. 4, lines 58-69). In addition, Marshall teaches the fermentation process to stimulate flavor production with the *Lactobacillus casei* *ssp. rhamnosus* organism in the presence of pyruvate, acetate or citrate as additives (col. 10, lines 17-35, 44-66). Jiménez discloses fermenting lupine seeds as discussed above.

Regarding Claims 18-20: Marshall discloses fermented oilseed products that are useful in imitation dairy food products, which includes ice cream, cream cheese, yogurt (i.e. probiotic food), sour cream, soymilk, cheese spreads, dips, among others (col. 1, lines 34-42; col. 2, lines 23-26). Probiotic foods recited in instant claim 19 are rendered obvious by Marshall's disclosure of yogurt. The preponderance of oilseeds that are disclosed by Marshall as producing diacetyl upon fermentation with the same microorganism and the inclusion of lupine in the Jimenez disclosure, having its own benefits, renders the use of lupine seeds in Marshall's invention obvious barring any evidence that shows otherwise.

Response to Arguments

3. Applicant's have overcome the 112 2nd rejection of claims 16 and 17, therefore the rejections have been withdrawn
4. Applicant's arguments filed 10/19/08 with regard to the rejections of claims 1-6, 8, 9, 16-22 under Marshall et al. (U.S. 4,678,673) and further in view of Holley et al. (U.S. 7,074,449) have been fully considered but they are not persuasive. However, the rejection has been withdrawn because

Holley reference does not reflect an appropriate prior art date. Upon further consideration, new grounds of rejection are made in view of **Marshall et al. (U.S. 4,678,673)** and further in view of **Jiménez et al. (Proceedings of the 9th International Lupin Conference June 2009 – Applicants' NPL)** and **Olmos-Dichara et al. (Biotechnology Letters, Vol. 19, No. 8, August 1997 pp 709-714)..**

5. Applicant's argue that lupine are legumes (beans) and are not oilseeds and that although soybean is a legume that all legumes are not oilseeds. The issue is not necessarily whether lupine is an oilseed but rather whether it would have been obvious to one of ordinary skill to substitute out the soybean for the lupine. Examiner agrees that lupine is not listed among "oilseed crops", which are crops grown primarily for their oil content as recited in Applicants' Exhibit A but this does not mean that lupine cannot be an adequate source of oil especially where it can contain up to 15% oil as discussed above in the Jiménez reference. Regarding Exhibit B, C and D, the fact that lupine is defined as a legume does not mean that it could not be used for its oil content especially where soybean is also a legume. Regarding Exhibit E where soybeans contain 19% fat and peanuts contain 15% and where the exhibit recites that lupine contain 4%, Examiner can see where upon reading the German Wikipedia article that the oil content in lupine is not as high soybean and peanuts. However, when read in light of the Jiménez reference, where lupines are known to contain upwards of 10 % and as high as 15% protein it further establishes the appropriateness of the substitution of soybean for lupine.

6. Further Applicants assert that it is pure speculation whether the lactic acid produced by *L. casei ssp. rhamnosus* is in the form of L-lactic acid. Applicants have provided no clear evidence regarding whether *L. casei ssp. rhamnosus* produces L-lactic acid as laid out on page 7 of Applicants' remarks. However, it is well known in the art that *L. casei ssp. rhamnosus* derived lactic acid contains

L-lactic acid. Additionally, prior art reference Olmos-Dichara is included in the new rejection and explicitly discloses that *L. casei ssp. rhamnosus* produces lactic acid and that 95% of the lactic acid produced is in the form of L-lactic acid [Table 1, pg 711].

7. Applicants assert that the fermentation time is shorter in Marshall than what is disclosed in the Specification and therefore the amounts in Marshall would not have the amounts of lactic acid as in the claims of the invention. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., fermentation time) are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Examiner points out that the claims are not directed toward a process but are instead product claims. Therefore, although Marshall may have used shorter fermentation times, the scope of Marshall in combination with Jiménez and Olmos-Dichara are commensurate with the claims where the product contains protein derived from lupine seeds, diacetyl, and lactic acid.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

Cerletti et al. J. American Oil Chemists' Society March 1999 vol.56 pg 460-463. where the advantageous of lupine seeds are discussed and its potential as an oilseed and substitution for soybean.

Sardjono et al. 1998 J. Agricultural Food Chem (pg. 3376-3380) where experiments involving fermentation of lupine confirms it as a potential replacement of soybeans in fermented food.

Wasche et al. (US 6,335,044) treatment of lupine seeds

Any inquiry concerning this communication or earlier communications from the examiner should be directed to FELICIA C. KING whose telephone number is (571)270-3733. The examiner can normally be reached on Mon- Thu 7:30 a.m.- 5:00 p.m.; Fri 7:30 a.m. - 4:00 p.m. alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jennifer McNeil can be reached on 571-272-1540. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/F. K./
Examiner, Art Unit 1794

/Jennifer McNeil/
Supervisory Patent Examiner, Art Unit 1794